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Pest Management Regulatory Agency

Annual Report 2013–2014

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Executive Summary

The Health Canada Pest Management Regulatory Agency (PMRA) is pleased to present the 2013–2014 Annual Report to Parliament, which details PMRA's accomplishments and activities over the past fiscal year. In 2013–2014, PMRA registered 12 new active ingredients, resulting in the registration of 33 new end-use products. As of 31 March, 2014, 15 new active ingredients were under joint review with other jurisdictions. Re-evaluation of older products continued, with three re-evaluations completed and one initiated this fiscal year, while 23 Special Reviews were initiated. In collaboration with the Regions and Programs Bureau (RAPB), PMRA also implemented a robust compliance and enforcement program. This included several compliance promotion activities, approximately 1000 inspections and over 1500 enforcement responses.

PMRA continued to allocate significant resources to the issue of honeybees and pollinators and the use of neonicotinoid pesticides in corn and soybean seed treatment in 2013–2014. Working with stakeholders domestically and internationally, PMRA initiated re-evaluation of this class of pesticides, implemented mitigation measures to control exposure, and contributed to the development of new pollinator risk assessments that will be used internationally.

PMRA developed a new cost recovery proposal to update our approach to collecting fees from registrants and to ensure more stable funding for important mandated health and environmental activities. PMRA continues to modernize its approach to regulating pesticides, with increased international collaboration on assessment and registration, implementation of new technology for data collection and analysis, and contribution to new risk assessment methodology. PMRA also continued its preparedness efforts concerning the Government's Single Window Initiative, under the Beyond the Border Action Plan.

Vision, Mission and About the PMRA

Vision

Continually promoting the highest standards for the protection of health and the environment, based on modern science, Health Canada has been an international force in the regulation of pesticides resulting in public confidence and improved access to safer and innovative pesticides for Canadians. PMRA has invested in its workforce, workplace and partnerships to support one of the best pesticide regulatory systems in the world.

Mission

Protecting the health and the environment of Canadians and supporting Canadian competitiveness by regulating pesticides and their use in an effective and transparent manner.

About the PMRA

PMRA is a branch of Health Canada and is responsible for regulating pest control products under the federal authority of the *Pest Control Products Act*. Our mandate is to prevent unacceptable risks to people and the environment from the use of these products. We also encourage the development and application of sustainable pest management strategies and facilitate access to lower risk pest control products. We use modern scientific assessment techniques to assess human and environmental health risks when evaluating and re-evaluating pest control products. PMRA endeavours to address public and stakeholder concerns, as well as to develop mechanisms to facilitate access to newer and safer products.

Core Regulatory Activities:
Protecting Canada, Protecting Canadians

Before a pesticide can be sold in Canada, pesticide registrants are required to provide PMRA with large volumes of data to show that their product does not pose unacceptable risks to health and the environment and that the product has value. These data are reviewed by PMRA scientists to determine whether a product is acceptable for registration in Canada. Developing a pesticide for use in the global marketplace can take several years and can cost manufacturers millions of dollars.

PMRA's science-based risk assessment includes the following:

- an examination of all sources and routes (oral, dermal, inhalation) of potential exposure to a given pesticide, including exposure through diet, from drinking water and from contact with treated areas like lawns and gardens;
- an estimation of the amount of pesticides that people, including children, may come in contact with, both during and after a pesticide application;
- a human health risk assessment based on the toxicity in relation to the amount of exposure in all potentially exposed special populations, including children; this considers the potential for a pesticide to cause adverse health effects such as cancer, birth defects and endocrine disruption, and allows registration only for those pesticides with exposures well below levels that cause adverse effects;
- an assessment of the fate and behaviour of a pesticide in the environment;
- an environmental risk assessment that considers risks to plants, birds, mammals, beneficial insects, aquatic organisms as well as fate in the environment; and,
- a value assessment that considers the contribution of the product to pest management, as well as its health, safety and environmental benefits, and social and economic impact.

PMRA follows timelines and standards for these evaluations as outlined in the "Management of Submissions Policy Process" (DIR2013-01). These processes vary with the type of registration submission (for an overview of product submission types please see Appendix Table 1), and the quantity of each submission type varies by year (Appendix Figure 1). PMRA has consistently met review timelines for most submission types over the last 3 years (Appendix Figure 2).

Science is continually evolving, and pesticide regulation is becoming an increasingly global activity. PMRA responds to these changes by incorporating scientific evaluation methods that meet the most modern standards, adapting regulations and registration processes to accommodate new pest management approaches, and playing an important role in the development and execution of international regulatory cooperation.

New Registrations

Products that meet PMRA's health and environmental requirements, and are shown to have value, are registered for use in Canada under the conditions stated on the label. There are different types of registered products, including agricultural (food and non-food), industrial and domestic products, and products that can only be applied by licensed professionals. PMRA has shifted towards conducting more product reviews in collaboration with other countries. This creates efficiencies in product evaluations, and increases access to important innovative products that might not otherwise be registered in Canada.

New Active Ingredients Registered in 2013–2014

In 2013–2014, 12 new active ingredients were registered for use in Canada, resulting in the registration of 33 new end-use products. Of the 12 new active ingredients, seven were biopesticides, three were conventional pesticides and two were antimicrobials (Appendix Figure 3). Please see Appendix Table 2 for a full list of new active ingredients registered, and their uses.

Joint Reviews

As of 31 March 2014, 15 new active ingredients were under joint review, including six conventional chemicals under Global Joint Review. In addition, there were five new proposals for the global joint review of new conventional chemical active ingredients pending applications for registration from industry.

Minor Uses

PMRA regularly meets with Agriculture and Agri-Food Canada's Pest Management Centre to provide regulatory advice that supports growers and grower associations in a collaborative process to identify priorities for new minor uses in Canada. PMRA also works directly with the provinces to assist in addressing the regional minor use needs. The Canadian Grower Priority Database enables stakeholders to communicate their pest control product priorities while providing PMRA with a vehicle for monitoring progress in bridging the technology gap. In 2013–2014, 84 regulatory decisions were made resulting in 458 new minor uses registered, of which 19 were joint reviews or workshares with regulators in other countries.

Emergency Registrations

A pest control product can be registered for up to one year for the emergency control of pest infestations for which no other effective method of control exists. The product must be effective, and the human health and environmental risks must be acceptable.

Emergency registrations are not intended as a solution to an ongoing pest-management problem. However, they may be reconsidered if the emergency situation exists in subsequent years and there is evidence that users and the sponsoring agencies are actively working towards satisfying the data requirements for registration.

Grower Requested Own Use

Grower Requested Own Use (GROU) is an initiative put in place by PMRA to make it easier for Canadian growers to access less expensive, equivalent pest control products available in the United States. Representatives of key grower associations sit on the GROU Nomination Committee and choose appropriate products for the program with input from member organizations. Thanks to this mechanism, growers with an approved import certificate can legally obtain the American version of a Canadian-registered product. Please see Appendix Table 3 for a list of approved GROU products for 2013–2014.

Other Registration and Regulatory Activities

PMRA continually seeks ways of adapting to changing technology, resources and stakeholder needs and expectations while ensuring protection of health and the environment. In 2013–2014, PMRA worked on several new and ongoing initiatives in this area.

Cost Recovery

PMRA established the current pesticide user fees in 1997. Although fees have not changed since, the overall cost of doing business has increased due to general cost of living increases, evolving science and risk assessment needs and a trend towards larger and more complex requests for registration. Changes in the way program activities are performed, including the growth and complexity of product submissions, have significantly increased costs.

In response to these changes, PMRA refined the application submission process, making it more efficient, effective, and predictable for applicants/registrants and the department. These efficiencies led to a reduction in certain costs, which will be reflected in the fee modernization.

Work to modernize the cost recovery regime in 2013–2014 included the completion of policy analysis, impact analyses and bilateral stakeholder consultations, resulting in the development of a fee proposal for broader public consultation.

Towards the end of March 2014, the *Pesticide Cost Recovery Consultation: A Consultation Document in Advance of Parliamentary Proposal* and Business Impact Test were published on the Health Canada website. Feedback from these documents will be considered for the next stage of the cost recovery initiative, which is to consult on a Pre-Proposal Notice ahead of formally tabling a proposal in Parliament. Stakeholders will continue to be engaged throughout the process in order to ensure timely implementation of the proposed fees.

International Cooperation

In collaboration with other federal partners, PMRA participated in the development of Canadian positions and submissions to international fora such as the Stockholm Convention. The Stockholm Convention is a legally binding international treaty that addresses international management of chemicals with the focus on production and use of persistent organic pollutants (POPs). Canada is a Party to this Convention.

The technical committee of the Convention is currently reviewing pentachlorophenol (PCP), a wood preservative registered in Canada under the authority of the *Pest Control Products Act*. PMRA is the responsible federal authority for meeting obligations and on-going participation at the Stockholm Convention as it pertains to pesticides.

PMRA continues with its efforts towards harmonizing pesticide regulatory systems for the purpose of improving product access and fostering an equal playing field in the North American context, while maintaining strong human and environmental health protection. PMRA hosted the NAFTA Technical Working Group Executive Board meeting and annual stakeholder session in Ottawa in November 2013.

PMRA provided input to a variety of Organisation for Economic Cooperation and Development (OECD) guidance documents/surveys/projects related to health evaluation and risk assessment.

Assessment of Chemicals with Persistent, Bioaccumulative, and Toxic Properties

In 2013–2014, PMRA worked with domestic and international partners to develop guidance for assessing bioaccumulation in aquatic organisms and the long-range transport of pesticides. PMRA also collaborated with Environment Canada to develop chemical dossiers prepared for the United Nations Environment Programme Stockholm Convention Persistent Organic Pollutant Review Committee supporting strong, science-based assessments consistent with domestic regulatory approaches. PMRA also participated in an international workshop with representation from academia, regulatory, and industry groups in order to explore existing laboratory protocols and guidance documents that could be used to develop a framework for assessment of bioaccumulation in terrestrial organisms.

International Guidance for Pesticide Field Dissipation Studies and Ecoregion Crosswalk

PMRA has co-led the development of two OECD eco-region guidance documents: *Harmonized international guidance for conducting pesticide terrestrial field dissipation studies* and *A Geographic Information System-based (GIS-based) model that allows comparison of North American & European eco-regions*. Together, these will allow optimum use of field studies on pesticides conducted on both continents, thus strengthening regulatory decisions and reducing regulatory burdens for both registrants and regulators.

In 2013–2014, PMRA collaborated with the United States Environmental Protection Agency and CropLife International to organize a symposium on "Terrestrial Field Dissipation Studies in Global Agrochemical Registration Programs" at the American Chemical Society National meeting where the guidance on conducting field studies and the associated eco-region model were presented to the pesticide industry and scientific community.

Maximum Residue Limits (MRLs)

PMRA is actively involved in ongoing MRL initiatives. These include participation in the WHO/FAO Joint Meeting of Pesticide Residues and serving as Head of Delegation to the Codex Committee on Pesticide Residues. Through these activities, PMRA engages in the coordination and promotion of Canadian objectives in setting international standards (Codex MRLs).

Through its involvement in the Regulatory Cooperation Council initiative, PMRA has undertaken the analysis of novel, scientific methodologies designed to further streamline the data requirements required to establish MRLs. These ongoing projects should also assist in further aligning MRLs for major and minor uses of pesticides to minimize trade barriers of pesticide-treated commodities between global partners.

Pollinators and Neonicotinoids

PMRA continued to receive bee mortality reports in 2013. The majority of bee reports in 2013 originated from Ontario with additional reports from Quebec and Manitoba. The PMRA worked very closely with the provinces to gather information from the affected beeyards, collect samples, and collect agricultural information to help evaluate the role pesticides may have played in the bee losses. In addition, PMRA evaluated the bee mortalities that were reported in 2012 and 2013 and concluded that exposure to neonicotinoid insecticides in dust that was generated while planting treated corn seeds was a contributing factor in the bee mortalities reported.

PMRA worked with multiple stakeholders, including the Canadian Seed Trade Association, beekeeper associations, the Association of Equipment Manufacturers, pesticide registrants, CropLife Canada, and the Grain Farmers of Ontario to develop measures to reduce exposure of pollinators to neonicotinoid dust. Subsequently, PMRA announced its intent to implement additional protective measures in a Notice of Intent (NOI) issued on 13 September 2013. These measures included the use of dust-reducing seed flow lubricants, adherence to safer seed planting practices, and new pesticide and seed packaging labels with enhanced warning statements. Almost 16 000 comments were received on the NOI, with 90 percent coming from the general public. The requirements of the NOI were implemented in advance of the 2014 growing season. PMRA, along with stakeholders, conducted multiple outreach activities to communicate the new requirements indicated in the NOI.

Pollinator activities are coordinated internationally through a number of different working groups. The OECD Working Group on Pesticides: Pesticide Effects on Insect Pollinators is co-led by Canada, the United States and Germany and provides a venue for communication of pollinator incidents, development of pollinator testing requirements and assessment methods, and communication of mitigation strategies for pollinator risks. Through the OECD Working Group

of the National Coordinators on the Test Guidelines Program, PMRA has contributed to the development of honey bee larvae toxicity study protocols. PMRA also contributes to the International Commission for Plant-Pollinator Relationships through which the risks posed to pollinators by pesticides are examined and guidance is being developed for risk assessment methods and study protocols including field and semi-field studies, larvae/brood studies, for both honeybees and other types of bees.

PMRA has collaborated with the United States Environmental Protection Agency and the California Department of Pesticide Regulation to develop a *North American Pollinator Risk Assessment Framework* with the help of a Pollinator Science Advisory Panel and has worked collaboratively to incorporate recommendations made by the panel into the risk assessment guidance to be used jointly by the Agencies, as well as develop harmonized data requirements for the pollinator risk assessment. The Agencies are also working collaboratively on the re-evaluation of three neonicotinoid pesticides focussed on the risk to pollinators.

Re-evaluation / Special Review Program

Under the *Pest Control Products Act*, re-evaluations of pesticide registration decisions are initiated at a minimum every 15 years. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, outlines the process being followed to consider any changes in the information required, or to the procedures used, to evaluate the health and environmental risk or value since the last major regulatory decision on a pesticide or group of pesticides. This ensures that registered pesticides continue to meet modern standards for health and environmental protection. In addition to the cyclical re-evaluation, special reviews are another mechanism under the *Pest Control Products Act* to determine the continued acceptability of registered pesticides where the review is focussed on addressing specific aspect(s) of concern (for example, concerns identified by an OECD member country which resulted in a prohibition of all uses).

During fiscal year 2013–2014, 1 re-evaluation and 23 special reviews were initiated in accordance with the *Pest Control Products Act*. In addition, three re-evaluations were completed with final decision documents published resulting in improved product use conditions to further protect human health and the environment. This corresponds to three end-use products affected. Consultations on a proposed special review decision on Compound 1080 and a proposed re-evaluation decision on clofentezine (a cooperative re-evaluation between the United States and Canada) were conducted during this fiscal year. Of particular note, a consultation document on the proposed approach for special reviews was published. Appendix Table 4 provides an overview of the numbers of re-evaluation and special review decisions made in 2013–2014, and these are further described in Appendix Table 5.

Also of note, risk management plans for products containing diazinon and products used as heavy duty wood preservatives were published outlining improved product use conditions to further protect human health and the environment. Additionally, considerable work was completed, in collaboration with stakeholders, provincial governments and growers, in

developing improved label information that further protects bystanders and the environment when soil fumigant products (containing the active ingredients chloropicrin, dazomet, metam sodium and metam potassium) are applied.

Transition Strategies

Phase-out of an active ingredient or use may present a number of complicating issues, which include the lack of viable alternatives to replace the phased-out uses, the loss of uses with a high value to public health or the economy, or a significant impact on a specific sector. For critical uses, these factors can present challenges in timely transition away from the actives or uses that are subject to phase-out. As part of the risk management approach and in order to ensure smooth phase-out of the actives or critical uses with risks of concern, PMRA organizes and facilitates a forum for growers, registrants, provincial coordinators and other stakeholders to discuss and to develop a transition strategy for the identification and adaptation to alternate lower risk pest management tools as solutions to uses lost as a result of phase-out.

In 2013–2014, 25 of the 136 prioritized crop/pest combinations identified by the working groups were addressed. In addition, two new groups (berries for diazinon/endosulfan and cucurbits and vegetables for endosulfan) were added to the existing transition strategies this past year.

Incident Reporting Program

The PMRA's Pesticide Incident Reporting Program has been collecting incident reports since April 2007. Incident reports are vital for detecting adverse effects, including those that are not evident during the initial registration of a pesticide.

The PMRA uses incident report data to identify and characterize potential risk to humans, domestic animals and the environment from the use of pesticides. Incident report assessments are prioritized based on the type of incident. Serious adverse effects (such as major effects or death) are evaluated immediately and mitigation measures are put into place if warranted. If a potential risk is identified, it is investigated and protective action may be taken, such as changes to how a pesticide is manufactured, packaged, labelled, or used. Incident report data also informs risk assessments for new registrations and re-evaluations. Monitoring incidents for unanticipated effects is an ongoing process that includes re-assessing previous conclusions, as necessary. In cases where mitigation strategies have been adopted, the PMRA also monitors incident report data to determine if the actions were effective in managing the identified risk.

In 2013–2014, 2019 incident reports were filed, 1274 of which occurred in Canada. Reporting levels are similar to 2012–2013, and details of these reports can be found on the Pesticides and Pest Management portion of the Health Canada website.

Assessments of incident reports over the 2013–2014 period have led to the following actions to date: revision of label instructions for a pesticide to reduce the potential for drift and, thereby, reduce the potential for bystander exposure; and follow-up compliance investigation of a pest control company for possible misuse of a pesticide that resulted in several people becoming ill.

Incident report data also flagged a possible risk of respiratory effects in one case, leading to new data requirements to mitigate this concern.

As in previous years, domestic animal incidents were the most frequent type of incident reported, followed by human and environmental incidents. Dermally applied spot-on type products for the control of fleas and ticks continue to figure prominently in domestic animal incidents. An analysis of incidents associated with the use of these products was initiated in 2009, resulting in the immediate publication of an advisory. In September of 2010, registrants were required to modify their product labels to include additional warnings to protect smaller animals, and to prevent the use of dog products containing permethrin on cats. Registrants were given 12 months from the date of notification to distribute or sell product with the previously approved label. Despite these actions, there has been a significant increase in the volume of reported incidents associated with these products. Increased awareness of the issue and of the incident reporting program has likely resulted in some of the observed increase. An evaluation of these incidents has been initiated by the PMRA in order to verify that the new risk mitigation measures put in place adequately minimise the risks associated with the use of these products. Further risk reduction measures will be implemented if our review supports such an action. Please see the *2012 Report on Pesticide Incidents* for additional details.

There were 27 human incident reports of high severity (death or major). Upon analysis of the human incidents classified as major effects or death, 19 incidents were either not considered to be related to pesticide exposure or there was insufficient information to evaluate them. The remaining eight incidents (four deaths and four major incidents) were considered to have some association to the reported pesticide exposure. All eight occurred in the United States. Two of the serious human incidents involved the accidental ingestion of paraquat. Due to the acute toxicity of paraquat, accidental ingestion of a small amount can be fatal. Based on these incident reports, as well as previous incident reports submitted for paraquat, the PMRA is developing risk mitigation measures to prevent the accidental ingestion of paraquat. Of the remaining six serious human incidents, four (three deaths, one major) were due to intentional ingestion of a pesticide; one incident was the result of the pesticide being accidentally sprayed in the subject's eye; and in the last incident, a young child (less than one year old) accidentally had access to an open bag of herbicide, he had dermal contact and possibly ingested some of the product. PMRA evaluated the circumstances of the incidents as well as the safety precautions and use directions on product labels and concluded that it was unlikely that these incidents could be mitigated through regulatory actions such as label changes. However, the database of incident reports is continually monitored and these conclusions will be re-assessed as warranted.

Environment incidents involving bees and neonicotinoids were also reported. These incidents were included as part of an extensive evaluation of honeybee mortalities. Measures to further reduce bee exposure to neonicotinoid pesticides during planting of treated corn and soybean seeds were to be implemented for the 2014 planting season. Additional information is available in this document in the section 'Pollinators and Neonicotinoids' and in the PMRA document *Update: Pollinator Protection and Responsible Use of Insecticide Treated Seed*, which is available on the Pesticides and Pest Management portion of the Health Canada website.

In cases where mitigation strategies are adopted, the PMRA monitors incident report data for a reduction in the number of incidents which could be associated with the actions taken. For example, a decrease in the number of reported Canadian incidents involving rodenticides was noted in 2013 compared to previous years. This decrease was noted mainly in domestic animal incidents involving bromadiolone, and may partially be attributed to the risk mitigation measures that PMRA required for rodenticides by the end of 2012 (Re-evaluation Note REV2010-17, *Risk Mitigation Measures for Eight Rodenticides*).

Chemicals Management Plan

Under the Government of Canada's Chemicals Management Plan, PMRA continues to collaborate with other government departments in the evaluation and risk management of chemical substances in Canada. For more information, please consult the Chemicals Management Plan webpage at http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php.

National Pesticide Compliance Program

PMRA's National Pesticide Compliance Program plays an important role in the protection of human health and the environment by promoting compliance with the *Pest Control Products Act*, and its regulations, among all regulated parties (registrants, distributors, growers, importers, manufacturers, formulators and users). This is done through robust and risk-focused compliance promotion, monitoring and inspection programs, and enforcement responses. These activities are conducted in partnership with Health Canada's Regions and Programs Bureau (RAPB), and in collaboration with federal and provincial partners. This program is an important mechanism for post-registration pesticide risk reduction.

Compliance promotion and inspection activities are prioritized annually on the basis of an assessment of risks to the health of Canadians and their environment. This is done through consultations within PMRA and with RAPB regional managers, who in turn consider information from provinces and territories. Upon approval of the National Pesticide Compliance Plan, RAPB implements this plan across the country, in close coordination with the PMRA.

PMRA and RAPB also respond to reported incidents of suspected non-compliance, and complaints received from the public and regulated parties. If instances of non-compliance with the *Pest Control Products Act* are detected, measures are taken appropriate to the circumstances and the risks involved. Enforcement responses can include enforcement letters, denials of entry into Canada, seizures and detentions, forfeitures, product registration amendments or cancellations, compliance orders, and administrative monetary penalties under the *Agriculture and Agri-Food Administrative Monetary Penalties Act*. Violators may also be subject to criminal prosecution under the *Pest Control Products Act*. PMRA's laboratory in Ottawa supports this work by analysing samples collected in the field for compliance with the *Pest Control Products Act*.

In 2013–2014, PMRA delivered eight national compliance promotion programs to measure and promote awareness about requirements under the *Pest Control Products Act* and its regulations. Examples include:

- Promoting proper use of personal protective equipment, in particular for migrant workers who may be at risk due to lack of awareness of label requirements related to postapplication protective measures.
- Educating users of phosphine fumigants on the need for a fumigation management plan and other new precautions that were added to labels in 2011 as a result of re-evaluation of these products.
- Measuring grower awareness of label changes to endosulfan, and follow-up with education as needed to promote safe use of this product.

In 2013–2014, 14 planned inspection programs were delivered. These covered a wide range of sectors including registrants, pesticides in the marketplace, commercial pest control operators, and pesticide users. Examples include:

- Monitoring of strychnine use in Alberta and Saskatchewan in response to reports of non-target animals being killed from misuse of the product.
- Education of tobacco and ginseng growers on proper use of chloropicrin products in response to three human health incidents in 2012, and monitoring for compliance with discontinuation of another soil fumigant, Telone.
- Continued inspections of pesticide use in aquaculture and livestock industries to ensure compliance with *Pest Control Products Act* regulations.

Approximately 1000 planned inspections were conducted, with more than 300 additional inspections conducted in response to complaints and incident reports. In total, 269 soil or other samples were submitted by regional inspectors to the PMRA laboratory to verify compliance with the *Pest Control Products Act*. Most of these inspections found high levels of compliance. In 2013–2014, most of the detected instances of non-compliance involved the possession of an unregistered product, as well as the sale, import, and use of unregistered products or use contrary to the label approved by PMRA. Most violations were among users of pesticides, followed by retailers, distributors, registrants and non-registrants.

In 2013–2014, the PMRA carried out approximately 1500 enforcement responses aimed at correcting non-compliance within the regulated community. These enforcement responses included 438 requests to address non-compliant products available in the marketplace or in the hands of users, 159 denials of entry into Canada for unregistered pesticides, 494 education and enforcement letters targeting the misuse of pesticides by users, and six notices of violation under the *Agriculture and Agri-Foods Administrative Monetary Penalties Act*. Three of the notices of violation were issued to address repeat violators distributing or importing unregistered pest control products and three others were to address improper packaging and misuse of pest control products by pest control operators. Most enforcement activities took place in the provinces of Ontario, Quebec and British Columbia.

Select regulated parties and individuals who have previously been known to be non-compliant with regulations, and for whom the risks of re-offense were significant, were followed up by 81 surveillance inspections in 2013–2014. As of 31 March 2014, 87 percent of these inspections found return to compliance. Health Canada is taking active steps, including application of escalated enforcement measures, to compel the remaining regulated parties and individuals to fully comply with the PCPA.

The PMRA also continued preparing for the implementation of the Government's Single Window Initiative under the Beyond the Border Action Plan. In 2013–2014, this included working with other Health Canada branches and key stakeholders on the Electronic Integrated Import Declaration that will collect program-specific data and eliminate paper-based declarations. Consultations and outreach activities were implemented to inform stakeholders of key aspects of the Single Window Initiative, and a strategy was developed to better identify and monitor volumes of pest control products crossing the border.

Finally, the PMRA continued to collaborate with its international regulatory partners to share and exchange compliance and enforcement information on pesticides under the OECD's Network of Officials for Pesticide Compliance and Enforcement.

For additional information, including a list of Enforcement Bulletins published, please refer to the National Pesticide Compliance Program webpage on Compliance and Enforcement at www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/compli-conform/index-eng.php.

Outreach Activities

PMRA's outreach program has three main functions: to develop and distribute material to professional and consumer audiences on all aspects of responsible pesticide use; manage a 1-800 information line and e-mail service to respond to enquiries on pesticides and pest management; and provide support and advice to regional office for the participation of RAPB regional officers at fairs, exhibits and other opportunities through the use of displays, didactic tools and printed material.

In 2013–2014, working closely with PMRA scientific teams, the outreach team produced and disseminated a variety of materials in response to current and emerging needs. Of particular note this past year, PMRA produced a poster on pesticide safety for seasonal and migrant workers. Descriptive text with the poster was made available in six different languages. The Pest Management Information Service responded to over 1800 calls and e-mails from the public on a broad range of questions relevant to pest management and responsible pesticide use. Regional compliance officials were able to attend over fifty fairs/exhibits across Canada, to engage the public in discussion about consumer pesticide products, and more specialized audiences such as grower groups and provincial partners.

In addition, in support of the Health Canada's efforts to address the new web content reduction and accessibility requirements, PMRA successfully coordinated the streamlining of PMRA's web content without compromising access to public documents.

PMRA provides the public with the opportunity to comment on proposed decisions in various areas. More than 150 documents were posted on the Health Canada website for public comment, including 29 Proposed Regulatory Decisions (PRDs), 5 Proposed Re-evaluation Decisions (PRVDs), and 114 Proposed Maximum Residue Limits (PMRLs).

Financial Profile

Financial Profile (in millions of dollars)	
A-Base	$ 27.4[1]
Revenue	$ 8.4
Growing Forward	$ 3.7
Chemicals Management Plan	$ 5.0
Total	**$ 44.5**

PMRA received $3.7M through the Growing Forward initiative to support the registration of minor use products. As a result, newer, more environmentally sustainable, and more modern products have been made available to Canadian producers, which helps sustain Canada's competitive position globally.

Through Canada's Chemicals Management Plan, PMRA is receiving $25M for fiscal years 2011–2012 to 2015–2016 to re-evaluate older pesticides, improve risk-management approaches through Incident Reporting and Sales Reporting regulations, and contribute to the development of scientific and regulatory approaches with other jurisdictions on high-priority issues.

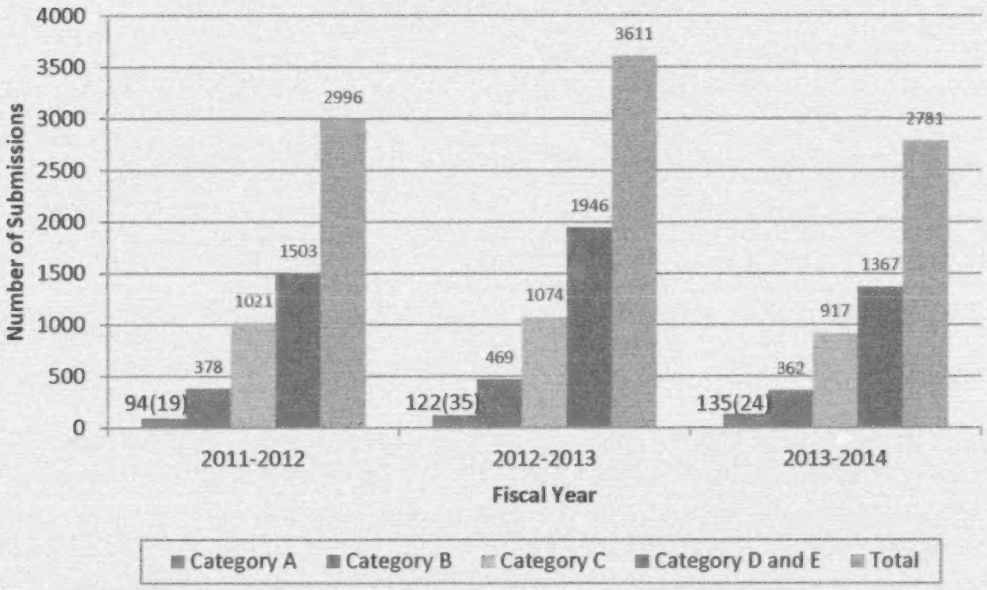
1 The 2012–2013 PMRA Annual Report misreported the A-Base funding as $34.1M. The correct figure for A-Base funding is $28.3M. Other figures, including the total ($44.9M), were reported correctly.

Appendices

Table 1 Product Submission Categories

Category A	Submissions to register new active ingredients and their companion end-use product(s); applications to add a major new use to a registered pesticide; submissions to establish a maximum residue limit for a previously non-assessed active ingredient; and submissions for user requested minor use registrations. Category A submissions require a full, supporting data package.
Category B	Submissions to amend a product label (for example, changes in application rates, timing of applications, new pests, changes to precautionary statements) or to change the product chemistry. Supporting data must be provided.
Category C	Submissions to register or amend a product label (add pest, use or change application rate) or change a formulation based on previously established precedents, or those that have reduced data requirements.
Category D	Submissions to register or amend products within particular programs such as the Import for Manufacture and Export, Own-Use Import, Grower Requested Own Use program, Master Copy, Private Label, User Requested Minor Use Label Expansion and renewal of registration.
Category E	Submissions for research authorizations and research notifications, when the research is carried out in Canada.

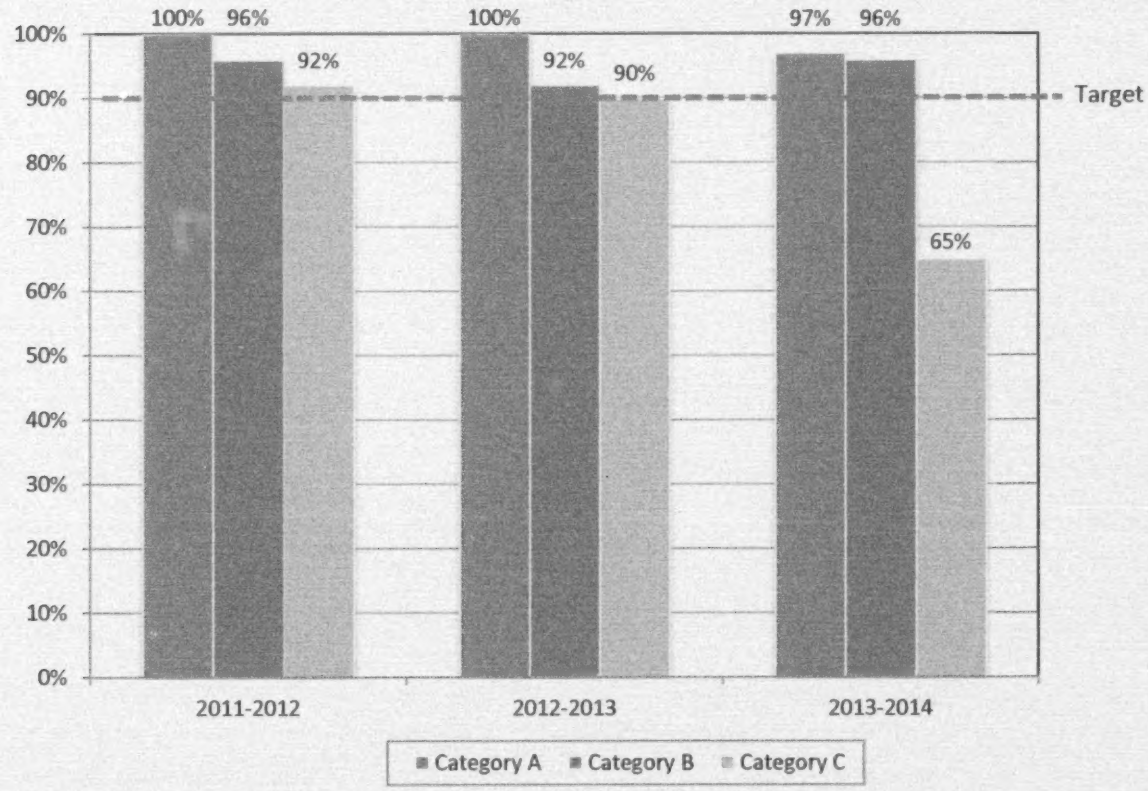
Figure 1 Number of Submissions Completed by PMRA for the period of 1 April 2011 to 31 March 2014



Trends and Limitations:

- Represents 12-month period
- Most Category A and many Category B submissions have >12 month timelines (therefore received in previous years)
- Number of submissions completed does not include pre-submission consultations, and includes Registered, Withdrawn and Rejected
- For Category A the number in parentheses is the number of new active ingredients completed

Figure 2 Performance against review Timelines for Category A, B and C Submissions Completed



Trends and Limitations:

- The Category C performance rate for 2013/14 is due to an increase in workload as a direct result of several re-evaluation decisions taken in 2011 and 2012. Re-evaluation decisions for major chemical use patterns may be implemented through a requirement for Category C submissions of label amendments.

Figure 3 Number of New Active Ingredients Registered by PMRA from 1 April 2011 to 31 March 2014

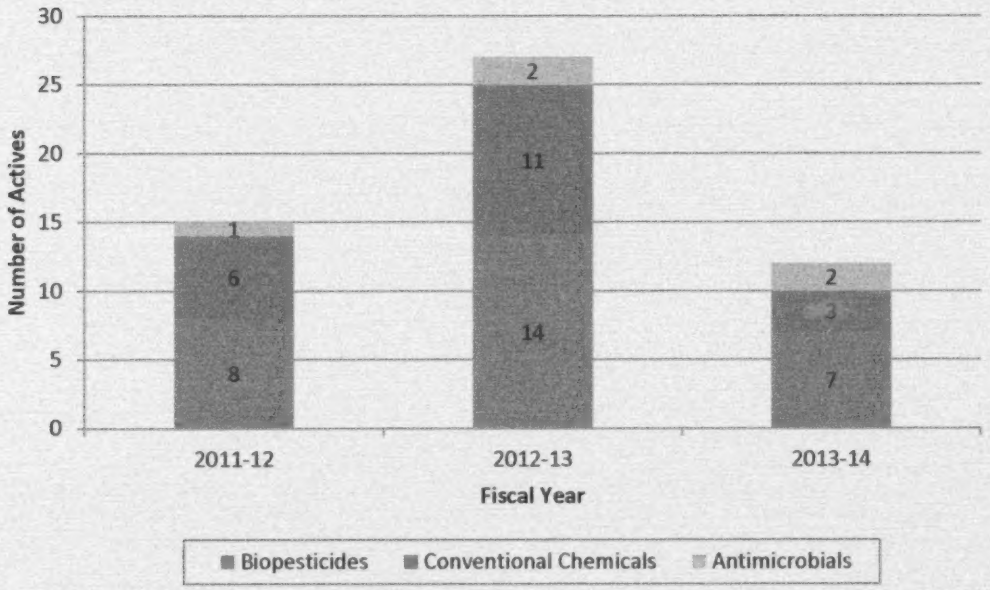


Table 2 New Active Ingredients Registered in 2013–2014

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
1	2-MethyL-4-isothiazolin-3-one	KORDEK(TM) LX 5000 INDUSTRIAL MICROBICIDE	Material Preservative	Full	Antimicrobial	Natural and synthetic polymer lattices, water-extendible metalworking fluids (soluble oil, semi-synthetic and synthetic types), water-extendible metalworking fluid concentrates (soluble oil, semi-synthetic and synthetic types).
		KORDEK(TM) MLX INDUSTRIAL MICROBICIDE	Material Preservative	Full	Antimicrobial	Natural and synthetic polymer latices, mineral dispersions,
		ROCIMA(TM) 550 INDUSTRIAL MICROBICIDE	Material Preservative	Full	Antimicrobial	Aqueous-based paints and coatings.
		NEOLONE(TM) M-10 INDUSTRIAL MICROBICIDE	Material Preservative	Full	Antimicrobial	Aqueous-based household products: detergent, cleaners, polishes and raw materials used to formulate them.
2	3-decen-2-one	SmartBlock®	Plant Growth Regulator	Full	Biopesticide	Potatoes
3	*Bacillus subtilis* (Strain GB03)	Kodiak Flowable Fungicide	Fungicide	Full	Biopesticide	Canola, mustard (oilseed and condiment) and rapeseed. **Crop Group 6 Legume Vegetables including soybeans:** Bean (includes grain lupin, sweet lupin, white lupin, white sweet lupin, field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean, adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean, blackeyed pea), broad bean, chickpea (garbanzo bean), guar, jackbean, lablab bean (hyacinth bean), lentil, pea (includes dwarf pea, edible-pod pea, English pea, field pea, garden pea, green pea, snow pea, sugar snap pea), pigeon pea, soybean (includes immature), sword bean
		Kodiak Concentrate Fungicide	Fungicide	Full	Biopesticide	
4	Chlorfenapyr	MYTHIC INSECTICIDE	Insecticide	Full	Conventional Chemical	Limited exterior application to buildings, pre-construction treatment (concrete slab-on-ground, crawl spaces, hollow block foundation or voids), post-construction soil treatment and treatment of structures with wells or cisterns
		PYLON MITICIDE INSECTICIDE	Insecticide	Full	Conventional Chemical	Greenhouse ornamentals including but not limited to african violet, geranium and petunia; greenhouse fruiting vegetables: eggplant, ground cherry, pepino, pepper, tomatillo and tomato.

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
5	Copper, Metallic	ANTIMICROBIAL COPPER ALLOYS GROUP I	Sanitizer	Full	Antimicrobial	Manufacture and fabrication of non-food contact touch surfaces components for use in: healthcare facilities, community facilities (public and commercial buildings), common areas in residential buildings (for example, apartment/condo buildings), mass transit facilities, kitchen and bathrooms in homes and apartments
		ANTIMICROBIAL COPPER ALLOYS GROUP II				
		ANTIMICROBIAL COPPER ALLOYS GROUP III				
		ANTIMICROBIAL COPPER ALLOYS GROUP IV				
		ANTIMICROBIAL COPPER ALLOYS GROUP V				
6	Cyantraniliprole	DUPONT™ VERIMARK™ Insecticide	Insecticide	Full	Conventional Chemical	Potatoes, **Brassica Vegetables - Crop Group 5:** Broccoli, Broccoli (Chinese), Broccoli raab, Brussels Sprouts, Cabbage, Cabbage (Chinese, bok choy), Cabbage (Chinese, napa), Cabbage (Chinese mustard, gai choy), Cauliflower, Cavalo broccolo, Collards, Kale, Kohlrabi, Mizuna, Mustard Greens, Mustard Spinach, Rape Greens.
		DUPONT BENEVIA Insecticide	Insecticide	Full	Conventional Chemical	Potatoes, **Crop Subgroup 20 – Oilseeds:** Borage; Calendula; Canola; Crambe; Cuphea; Echium; Euphorbia; Evening Primrose; Flax seed; Gold of Pleasure; Hare's ear mustard; Lesquerella; Lunaria; Meadowfoam; Milkweed; Mustard seed; Niger seed; Oil radish; Poppy seed; Rapeseed; Rose hip; Safflower; Stokes Aster; Sunflower; Sweet rocket; Tea oil plant.
		DuPont Lumiderm Insecticide Seed Treatment	Insecticide	Full	Conventional Chemical	Canola, rapeseed, oilseed mustard.
		DUPONT EXIREL Insecticide	Insecticide	Full	Conventional Chemical	**Tuberous And Corm Vegetables – Crop Sub-Group 1C:** Arrowroot; Artichoke, Chinese; Artichoke, Jerusalem; Chufa Dasheen (taro); Ginger; Potato; Sweet potato; **Bulb Vegetables – Crop Group 3-07:** Chive, Chinese; Chive, fresh leaves; Daylily, bulb; Elegans hosta; Fritillaria; Garlic, bulb; Garlic, great-headed, bulb; Garlic, serpent, bulb; Kurrat; Lady's leek; Leek; Lily; Onion, Beltsville bunching; Onion, bulb; Onion, Chinese, bulb; Onion, fresh; Onion, green; Onion, macrostem; Onion, pearl; Onion, potato, bulb; Onion, tree, tops; Onion, Welsh, tops; Shallot, bulb; Shallot, fresh leaves; Wild leek; **Leafy Vegetables – Crop Group 4:** Amaranth (leafy amaranth, Chinese spinach, tampala); Arugula (Roquette); Cardoon; Celery; Celery, Chinese; Celtuce; Chervil; Chrysanthemum, edible-leaved; Chrysanthemum, garland; Corn

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
						salad; Cress, garden; Cress, upland (yellow rocket, winter cress); Dandelion; Dock (sorrel); Endive (escarole); Fennel, Florence (finochio); Lettuce, head and leaf; Orach; Parsley; Purslane, garden; Purslane, winter; Radicchio (red chicory); Rhubarb; Spinach; Spinach, New Zealand; Spinach, vine; Swiss chard; **Brassica Vegetables - Crop Group 5:** Broccoli; Broccoli, Chinese; Broccoli raab; Brussels sprouts; Cabbage; Cabbage, Chinese (bok choi); Cabbage, Chinese (napa); Cabbage, Chinese, mustard (gai choi); Cauliflower; Cavolo broccolo; Collards; Kale; Kohlrabi; Mizuna; Mustard greens; Mustard spinach; Rape greens; **Fruiting Vegetables (Except Cucurbits) – Crop Group 8-09:** African eggplant; Currant tomato; Eggplant; Garden huckleberry; Goji berry; Groundcherry; Martynia; Okra; Pea eggplant; Pepino; Pepper, bell; Pepper, nonbell; Scarlet eggplant; Sunberry; Tomatillo; Tomato; Cultivars, varieties and/or hybrids of these; **Cucurbit Vegetables – Crop Group 9:** Chinese waxgourd (Chinese preserving melon); Citron melon; Cucumber; Gherkin; Gourd, edible (includes Chinese okra, cucuzza, hechima, hyotan); Momordica spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber); Muskmelon (includes cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melon); Pumpkin; Squash, summer (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); Squash, winter (includes acorn squash, buttermut squash, calabaza, hubbard squash, spaghetti squash); Watermelon; **Pome Fruits – Crop Group 11-09:** Apple; Azarole; Crabapple; Mayhaw; Medlar; Pear; Pear, Asian; Quince; Quince, Japanese; Cultivars, varieties and/or hybrids of these; **Stone Fruits – Crop Group 12-09:** Apricot; Cherry, black; Cherry, Nanking; Cherry, sweet; Cherry, tart; Chokecherry; Nectarine; Peach; Plum; Plum, American; Plum, beach; Plum, Canada; Plum, cherry; Plum, Chickasaw; Plum, Damson; Plum, Japanese; Plum, Klamath; Plum,

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
						prune; Plumcot; Sloe; Cultivars, varieties and/or hybrids of these; **Bushberries – Crop Sub-Group 13-07b:** Aronia berry; Blueberry, highbush; Blueberry, lowbush; Buffalo currant; Currant, black; Currant, red; Elderberry; European barberry; Gooseberry; Highbush cranberry; Honeysuckle, edible; Huckleberry; Jostaberry; Juneberry (Saskatoon berry); Lingonberry; Native currant; Salal; Sea buckthorn; Cultivars, varieties and/or hybrids of these; **Tree Nuts – Crop Group 14-11:** Almond; Beech nut; Bur oak; Butternut; Chestnut; Chinquapin; Ginkgo; Hazelnut (Filbert); Heartnut; Hickory nut; Monkey puzzle nut; Pecan; Walnut, black; Walnut, English
		FORTENZA RED	Insecticide	Conditional	Conventional Chemical	Potato seed
		FORTENZA	Insecticide	Conditional	Conventional Chemical	Potato seed
		MINECTO DUO 40WG	Insecticide	Conditional	Conventional Chemical	**Crop Group 4: Leafy Vegetables** – amaranth (leafy amaranth, Chinese spinach, tampala), arugula (roquette), cardoon, celery, Chinese celery, celtuce, chervil, edible-leaved chrysanthemum, garland chrysanthemum, corn salad, garden cress, upland cress, dandelion, dock (sorrel), endive (escarole), Florence fennel, head and leaf lettuce, orach, parsley, garden purslane, winter purslane, radicchio (red chicory), rhubarb, spinach, New Zealand spinach, vine spinach and Swiss chard; **Crop Group 5: Brassica Vegetables** –broccoli, Chinese broccoli (gailon), broccoli raab (rapini), Brussels sprouts, cabbage, Chinese cabbage (bok choy), Chinese cabbage (napa), Chinese mustard cabbage (gai choy), cauliflower, cavolo broccolo, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach and rape greens; **Crop Group 8-09: Fruiting Vegetables** – African eggplant, currant tomato, eggplant, garden huckleberry, goji berry, groundcherry, martynia, okra, pea eggplant, pepino, bell pepper, non-bell pepper, scarlet eggplant, sunberry, tomatillo, tomato, and cultivars, varieties and hybrids of these commodities; **Crop Group 9: Cucurbit Vegetables** – Chinese waxgourd (Chinese preserving melon), citron melon, cucumber, gherkin, edible gourd (includes hyotan, cucuzza, hechima, Chinese okra), Momordica spp. (includes

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
						balsam apple, balsam pear, bitter melon, Chinese cucumber), muskmelon (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon and snake melon), pumpkin, summer squash (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini), winter squash (includes butternut squash, calabaza, hubbard squash acorn squash, spaghetti squash), watermelon; Potatoes;
		MAINSPRING INSECTICIDE	Insecticide	Conditional	Conventional Chemical	Greenhouse ornamentals and outdoor ornamentals
7	Garlic Juice	Mosquito Barrier	Insect Repellent	Full	Biopesticide	Areas that attract mosquitoes such as grass, plants, shrubs and under decks and porches
8	Halosulfuron (Present as methyl ester)	SANDEA Herbicide	Herbicide	Full	Conventional Chemical	Apples; caneberries (blackberry, loganberry, red and black raspberry); highbush blueberries; rhubarb; asparagus; chile, bell and banana peppers; eggplant; tomatillo; pepino; groundcherry; cucumbers(including pickles); cantaloupes; honeydews; crenshaw melons; watermelon; pumpkins; winter squash; summer squash for processing; succulent snap beans; tomatoes; okra; tree nuts(beechnuts, butternuts, chestnuts, filberts(hazelnuts), hickory nuts, pecans, walnuts(black and English);
		PERMIT Herbicide	Herbicide	Full	Conventional Chemical	Dry beans; sweetcorn; popcorn; field corn; field corn grown for seed; grain sorghum(milo); proso millet;
		SedgeHammer Turf Herbicide	Herbicide	Full	Conventional Chemical	Commercial and residential turf and other non-crop sites including: airports, cemeteries, fallow areas, golf courses, landscaped areas, public recreation areas, residential property, roadsides, school grounds, sports fields, landscaped areas with established woody ornamentals, container and field nurseries, fairgrounds, race tracks, tennis courts, campgrounds and rights-of-way. Established turfgrasses: Bentgrass, creeping; Fescues, fine (creeping red, chewings, hard, sheep); Ryegrass, perennial; Bluegrass, Kentucky; Fescue, tall. Established woody ornamentals in landscaped areas Field grown ornamental production nurseries: Established Shrubs - Littleleaf boxwood, Japanese boxwood, Korean boxwood,

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
						Wintercreeper euonymus, Gardenia, Panicled hydrangea, Dwarf buford holly, Japanese holly, Dwarf yaupon holly, Yellow anise, Chinese juniper, Shore juniper, Creeping juniper, Rhododendron, Azalea, Kurume azalea, Formosa azalea, Bumald spirea, White lace spirea, Japanese spirea, American arborvitae. Established Trees - Meserve holly, Round leaf holly, Winterberry holly, Crape myrtle, Southern magnolia, Star magnolia, Austrian pine, Red pine, White pine, Loblolly pine, Holly oak, Northern red oak, Southern live oak Container grown ornamental production nurseries Renovation treatments prior to the establishment of turfgrass or woody ornamental plants Roadsides, right of way, tank farms, lumberyards, fuel storage areas, renovated areas, and fence rows.
9	P-Menthane-3,8-Diol and Related Oil of Lemon Eucalyptus Compounds	Citrepel Insect Repellent 30	Insect Repellent	Full	Biopesticide	Human skin.
		Natrapel Insect Repellent	Insect Repellent	Full	Biopesticide	Human skin.
10	Sodium Lauryl Sulfate	MTDX-CR	Insecticide	Full	Biopesticide	In and around buildings.
11	*Streptomyces acidiscabies* Strain RL-110T cells and spent fermentation media	OPPORTUNE PTO	Herbicide	Full	Biopesticide	Turfgrass (fescues and Kentucky bluegrass)
12	Tea Tree Oil	TIMOREX GOLD	Fungicide	Conditional	Biopesticide	Grape, greenhouse tomato, greenhouse pepper, greenhouse cucumber, Cucurbit vegetables crop group (field and greenhouse) except cucumber, strawberry.

Table 3 Approved GROU Products 2014

In 2013–2014, 21 products were available under the GROU Program:

Princep Nine-T Herbicide (Registration Number 16370)

Elevate 50 WDG Fungicide (Registration Number 25900)

Velpar L Herbicide (Registration Number 18197)

FirstRate Herbicide (Registration Number 26697)

Oracle Dicamba Agricultural Herbicide (Registration Number 26722)

Apollo SC Ovicidal Miticide (Registration Number 21035)

Agri-mek 1.9% EC Insecticide/Miticide (Registration Number 24551)

Pursuit 240 (Registration Number 23844)

Pursuit Herbicide (Registration Number 21537)

B-Nine WSG (Registration Number 17465)

SePRO A-Rest Solution (Registration Number 16393)

SUMAGIC Plant Growth Regulator (Registration Number 25781)

Bonzi Plant Growth Regulator (Registration Number 25453)

Prowl 400 EC Herbicide (Registration Number 23439)

Assure II Herbicide (Registration Number 25462)

Reglone Desiccant (Registration Number 26396)

Aatrex Liquid 480 (Registration Number 18450)

Reflex Liquid Herbicide (Registration Number 24779)

Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (Registration Number 27487)

Banvel II Herbicide (Registration Number 23957)

Basagran Liquid Herbicide (Registration Number 12221)

Table 4 Re-evaluation / Special Review Activities as of 31 March 2014

Re-evaluation/Special Review Decisions in 2013–2014				
	Final[1] Decisions	Proposed[2] Decisions	Pending[3] Publication	Total Decisions
Active ingredients reviewed	3	7	2	12
Discontinued/withdrawn by registrant	0	0	0	0
Phase-out requested (or proposed for phase-out) as a result of PMRA review	0	0	0	0
Registration continued—label modifications	2	7	1	10
Registration continued—no label modifications	1	0	1	2

1 PMRA has finalized the decisions for these products.
2 PMRA has published the proposed decisions.
3 Assessments have been completed and decisions proposed, but PMRA has not yet published the proposed decisions.

Table 5 Re-evaluation / Special Review Decisions in 2013–2014

No.	Active Ingredient	Publication Type	Summary of Decision or Proposed Decision (as contained in PRVD, RVD or REV note)
1	Myclobutanil	RVD2013-01	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
2	Ethylene Oxide	RVD2013-02	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
3	z-11-tetradecenyl acetate	REV2013-03	**Final Decision:** Re-evaluation not required. Acceptable for continued registration.
4	Mancozeb	PRVD2013-01	**Proposed Decision:** Proposed continued registration for most uses with implementation of new/revised mitigation measures and submission of data requirements. Phase-out of certain uses with risk concerns is proposed.
5	Nucleopolyhedrovirus for Gypsy Moth Larvae	PRVD2013-02	**Proposed Decision:** Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
6	p-Chloro-m-cresol	PRVD2013-03	**Proposed Decision:** Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
7	Sodium p-Chloro-m-cresolate	PRVD2013-03	**Proposed Decision:** Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
8	Paclobutrazol	PRVD2013-04	**Proposed Decision:** Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
9	Clofentezine	PRVD2013-05	**Proposed Decision:** Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
10	Compound 1080 (Special Review)	REV2013-04	**Proposed Decision:** Proposed for continued registration with implementation of new/revised mitigation measures to further protect the environment.